

**EXHIBIT XV**

## **EXHIBIT XV**

### **FOURTH QUARTER 2001**

<b>ACTIVITY/ DOCUMENT TYPE</b>	<b>SUBJECT</b>
NDA	Schering submission of NDA 21-445 for Zetia (ezetimibe).
Letter to FDA	Schering submission of field copy of cover letter for NDA (NJ District Office) and field copy of technical section of the NDA (Puerto Rico District Office).

### **FIRST QUARTER 2002**

<b>ACTIVITY/ DOCUMENT TYPE</b>	<b>SUBJECT</b>
Letter to FDA	Schering response to request for document outlining significance test used for screening adverse event date for the ISS.
Letter from FDA	FDA acknowledgement of Zetia NDA submission and assigning number 21-445 to NDA.
Letter to FDA	Schering original signed Patent Information and Debarment Certification.
Letter to FDA	Schering response to request regarding investigators for Phase III controlled studies and protocol numbers and titles of included studies.
Letter to FDA	Schering NDA Amendment: additional financial disclosure information.
Letter from FDA	FDA acknowledgement of standard review status and of user fee goal date of 10/27/2002.
Letter from FDA	FDA minutes of 2/6/2002 telephone meeting regarding sponsor's request for priority review.
Letter from FDA	FDA e-mail from safety reviewer (Stadel) requesting comments on draft of first part of safety review for Zetia and indicating that availability of information about recruitment of patients into 12 randomized clinical trials of Zetia be evaluated.

<b>ACTIVITY/ DOCUMENT TYPE</b>	<b>SUBJECT</b>
Letter to FDA	Schering NDA Amendment: complete reports for two nonclinical studies to replace incomplete studies submitted in section 5d of the Nonclinical Pharmacology and Toxicology section of NDA.
Letter from FDA	Request for Information from statistical reviewer.
Letter to FDA	Schering submission of two binders containing requested information relevant to audit sites as per discussion of 2/27/2002.
Letter to FDA	Schering response to request regarding 13 patients cited in the ISS.

## SECOND QUARTER 2002

<b>ACTIVITY/ DOCUMENT TYPE</b>	<b>SUBJECT</b>
Letter to FDA	Schering response to request for information regarding dates of data analysis plan (DAP) finalization and database lock for studies.
Letter to FDA	Schering response to request for additional information for studies.
Letter from FDA	Clinical Trials Data Bank.
Letter to FDA	Schering response to request regarding recruitment of patients into 12 randomized control Phase 2/3 studies.
Letter to FDA	Schering response to request for additional information for studies.
Letter to FDA	Schering proposed changes to safety review.
Letter to FDA	Schering four-month safety update.
Letter to FDA	Schering general correspondence regarding studies to support future combination product.
Letter to FDA	Schering general correspondence authorizing FDA to cross-reference the information contained in IND 52,791 and NDA 21-445 in support of IND submitted by Victor Navarro, M.D.
Letter to FDA	Schering response to 03/06/2002 request for additional information for studies.

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering general correspondence regarding preliminary results of study.
Letter from FDA	FDA request for information from biometric reviewer and pharmacology/toxicology reviewer.
Letter from FDA	FDA request for information listing items discussed on 5/3/2002 that are currently pending and requesting additional information.
Letter to NDA	Schering 15-Day fourth follow-up safety report.
Letter from FDA	FDA request for information requesting prompt written response in order evaluation of NDA to continue (extension of 5/23/2002 discussion of 5/20/2002 request for information).
Letter to FDA	Schering response to 5/23/2002 FDA request for additional information.
Letter to FDA	Schering response to 4/11/2002 FDA request that information regarding safety report 2001-09-0042 from study P00693 submitted to IND 52,791 be submitted to NDA 21-445 and requesting hospital records and autopsy reports including copy of fourth follow-up of safety report submitted to IND 52,791 on 6/11/2002, two emergency room reports, and note that Schering has been unable to obtain autopsy reports despite repeated inquiries.
Letter to FDA	Schering response to 7/11/2002 FDA request for additional information regarding subject NDA.

### THIRD QUARTER 2002

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering response to 2/27/2002 FDA request that potential drug interaction between ezetimibe and pioglitazone or rosiglitazone be studied. MSP conducted <i>in vitro</i> assay to assess ezetimibe inhibition of CYP2C8 and results were submitted to IND on 6/21/2002. Incorporated into NDA.
Letter to FDA	Schering response to 5/20/2002 FDA request, subsequently discussed on 5/23/2002 and in second letter on 6/13/2002.

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter from FDA	FDA letter confirming that proposed proprietary name, Zetia, is not recommended because of sound-alike similarity to previously approved drug Zebeta.
Letter to FDA	Schering submission of documents supporting that both parent compound and glucuronide significantly inhibit cholesterol absorption as per Schering's offer at 4/8/2002 IND meeting to discuss bioequivalence strategy for proposed combination tablet. Schering's offer to submit documents supporting statement that both parent compound and glucuronide significantly inhibit cholesterol absorption.
Letter to FDA	Schering letter containing arguments and reports in response to 7/9/2002 FDA letter recommending against use of trademark Zetia.
Letter to FDA	Schering response to 7/17/2002 FDA request for clarification of some items in submission of 5/9/2001 containing revisions to Figures 6.31 and 6.3b.
Letter to FDA	Schering NDA Amendment: amendment clarifying errors in original NDA CMC submission documents referred to in 05/16/2002 phone conversation and noting that changes do not alter the overall conclusions of the reports.
Letter to FDA	Schering submission of field copy of NDA CMC Amendment (Puerto Rico District Office).
Letter from FDA	Copy of current draft of Zetia safety review, requesting comments on technical accuracy or other matters.
Letter to FDA	Schering response to 6/28/2002 FDA request for information related to ezetimibe's effect on stool lipid.
Two Letters from FDA	FDA clarification of request of 7/30/2002.
Letter to FDA	Schering response to 5/20/2002 request from the biometrics and toxicology reviewers; subsequently discussed on 05/23/2002 and in a second letter, dated 6/13/2002, that rat and mouse SCH 58235 carcinogenicity tumor data be reanalyzed using by Tarone's test using historical data.
Letter to FDA	Response to 7/24/2002 FDA request for information on p values and clarification on items from protocols.
Letter to FDA	Schering response to FDA request for comments on and changes to 7/29/2002 draft safety review.
Letter to FDA	Schering Eight-Month Safety Update.

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering response to FDA request for information as summarized in a discussion on 8/16/2002.
Two Letters to FDA	Schering response to item 1 7/30/2002 FDA request for information and a clarification of those requests on 8/02/2002.
Letter to FDA	Schering response to the remaining items 2 & 3 of the 7/30/2002 FDA request for information and a clarification of those requests on 08/02/2002.
Letter to FDA	Schering response to 9/5/2002 FDA request that it stratify the analyses of CPK evaluation in males, in females, and in non-Caucasians, by actual race and 9/6/2002 request for a statement on the choice of 0-12-mU/ml as reference range for creatine phosphokinase.
Letter to FDA	Schering response to items 1 & 2 of 9/5/2002 FDA request regarding further efficacy analyses in non-Caucasians by specific race.
Letter to FDA	Schering response to 9/9/2002 FDA request for additional datasets containing efficacy data from studies.
Letter to FDA	Schering response to 9/23/2002 FDA request for p-values of the secondary efficacy variables to three and preferably four significant figures.
Letter from FDA	FDA Discipline Review Letter identifying deficiencies in the CMC section of the NDA.
Letter to FDA	Schering response to item 3 of 9/5/2002 FDA request that it provide a measure of subject compliance with diet in Caucasians, non-Caucasians, and non-Caucasians by specific racial subgroup.
Letter to FDA	Schering response to 9/11, 9/25 and 9/26/2002 FDA requests for additional financial disclosure information from Schering on studies and additional <i>p</i> values for mean triglycerides and total cholesterol.
Letter from FDA	FDA minutes of 7/23/2002 meeting to discuss use of Zetia trademark documenting Division's determination that Zetia is an acceptable tradename.
Letter to FDA	Schering letter responding to points 1 & 2 of 9/24/2002 FDA Discipline Review Letter and informing FDA that responses to Points 3-17 "will be provided under separate cover by the end of October."

## FOURTH QUARTER 2002

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering response to 9/23/2002 FDA request for data on the serum concentrations of vitamins that a statement in section 12.4.4 of the interim report for P00476 submitted on 12/24/2002 indicates were available at that time.
Letter to FDA	Schering response to FDA request for a summary statement regarding the data regarding dietary compliance by subgroup submitted on 9/25/2002.
Letter to FDA	Schering CMC Amendment: amendment of minor discrepancies identified in the Container/Closure information for Cotton Coil and the 388 mm continuous thread closure.
Letter to FDA	Schering submission of field copy of 10/03/02 CMC Amendment (Puerto Rico and NJ District Office).
Letter from FDA	FDA Discipline Review Letter regarding review of CMC section of NDA (fax & original).
Letter from FDA	FDA comments on Zetia patient package insert (PPI).
Letter to FDA	Schering response to 10/3/2002 fax commenting on packaging component for Zetia, accepting FDA's recommendations with two noted exceptions.
Letter to FDA	Schering revised text for PPI leaflet.
Letter to FDA	Schering response to 10/18/2002 telephone request for information confirming Phase IV commitment to provide efficacy and safety information from non-Caucasian patients treated with Zetia.
Letter to FDA	Schering response to request for information in response to 10/21/2002 teleconference and in reference to the Schering submissions of 10/1, 10/2, 10/3, and 10/22/2002.
Letter to FDA	Schering response to 9/23/2002 FDA request for data on the serum concentration of vitamins providing data for 1,25 dihydroxy vitamin D not available at time of Schering 10/1/2002 submission.
Letter to FDA	Schering final proposed package insert and PPI for Zetia.
Letter to FDA	Schering submission of summary statistics for 1,25 dihydroxy vitamin D in response to 9/23/2002 FDA request.
Letter from FDA	FDA approval of Zetia NDA 21-445.